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(71) Applicant: FUSION MEDICAL TECHNOLOGIES, INC. [US/US]; 1615 Plymouth Street, Mountain View, CA 94043 (US).

(72) Inventor: TUCKER, Robert; 3082 Meadow Road, N.E., North Liberty, IA 52317 (US).

(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew L.L.P., 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).

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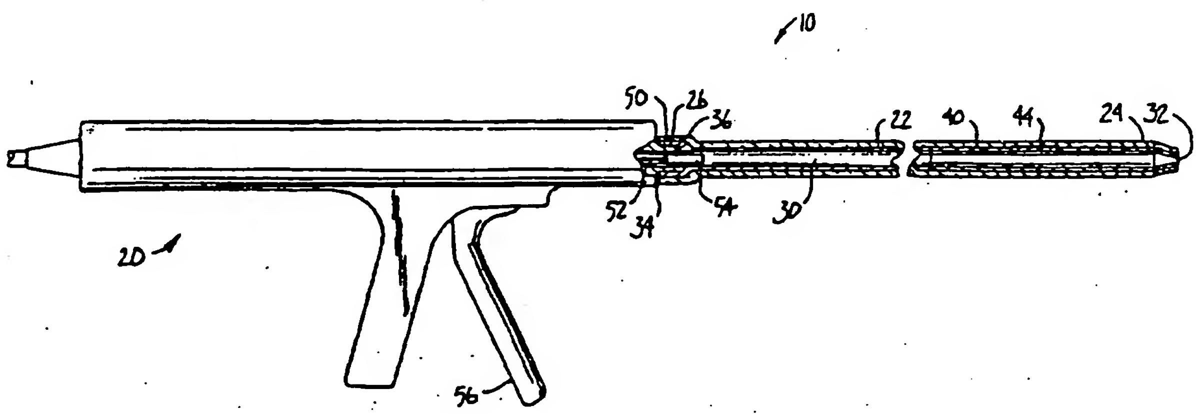
(54) Title: DEVICE AND METHOD FOR SEALING TISSUE



(57) Abstract

An apparatus and method for effecting and enhancing wound closure in tissue is disclosed. Wounds and tissue are sealed by heating a sealant material, such as collagen, in an applicator (10) to a temperature sufficient to melt the sealant. The melted sealant is then extruded through a distal tip of an elongate shaft (22) and applied to the target site, where it cools and sets to form bonds with the underlying tissue. The heated sealant flows over the wound to create an effective barrier against further blood leakage and, upon cooling, it readily adheres to the tissue to seal the wound. In addition, since high intensity energy is not applied directly to the wound, damage or destruction of neighboring tissue is minimized.

DEVICE AND METHOD FOR SEALING TISSUE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to devices, articles, and methods for effecting and enhancing wound closure in tissue. More particularly, the present invention relates to a method and apparatus for heating a sealant material and applying the heated sealant to tissue to close wounds and to join severed vessels.

Most surgical disciplines are concerned with the repair of damaged tissues and vessels. Tissue damage can be the result of direct trauma to the body or as part of a surgical procedure in which there is a separation of normally continuous tissue such as blood vessels. Historically, suturing has been the accepted technique for rejoining severed tissues and closing wounds. To suture a wound, the surgeon manually stitches the surrounding tissue with a surgical needle and suturing thread, and more recently, with a variety of polymeric or metallic staples.

While suturing and stapling techniques are often successful, there are a number of limitations inherent in such mechanical approaches. The practice of suturing or stapling tissue together not only requires significant skill, but is a relatively slow process, particularly when extensive repair is required or when anastomosing tiny biological structures. Even when suturing is properly performed, however, this technique can be less than satisfactory because of the gaps which are left between the stitches and the possibility of progressive structural weakening over time. For example, the gaps leave the wound open to bacteria, producing a risk of infection. In addition, the suture needle or staples puncture the tissue, producing holes through which biological fluid may leak.

absorbed by the damaged tissue. The heat produced by absorption of the optical energy converts biological tissue into a denatured proteinaceous substance which forms a biological glue that closes the wound. Similar to cauterization techniques, however, the high intensity optical energy in this procedure creates a substantial risk of damaging neighboring tissues.

For these and other reasons, it would be desirable to provide procedures for effectively sealing damaged tissue structures, such as torn vessels or open wounds. These procedures should be capable of forming an immediate closure of the damaged tissue to prevent further blood leakage and creating a permanent seal around the wound, while minimizing damage or destruction of surrounding tissue.

2. Description of the Background Art

U.S. Patent Nos. 4,854,320 and 5,140,984 describe the use of laser emitted optical energy to heat biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a "biological glue" to seal the tissue. PCT Application WO 94/21324 describes an applicator for introducing a fluent prepolymer liquid onto a wound. The prepolymer is then heated in situ to solidify the prepolymer, thereby creating a bond with the tissue. U.S. Patent No. 4,034,750 describes a method for electrochemically-linking collagen membranes to the damaged collagen fibrils of an animal body. U.S. Patent No. 5,156,613, PCT Application WO 92/14513, and copending Application Serial No. 08/231,998, assigned to the assignee of the present invention, describe a method for joining or reconstructing tissue by applying energy to a tissue site in the presence of a collagen filler material. Copending Application Serial No. 08/370,552 describes the use of an inert gas beam energy source for fusing collagen and other materials to tissue for joining or reconstructing the tissue. U.S. Patent No. 5,071,417 describes the application of laser energy to biological materials to seal anastomoses.

heating element (which is suitably coupled to the source of energy). The applicator preferably comprises a handle attached to the proximal end of an elongate shaft and an actuating mechanism, such as a plunger, for discharging the sealant from the distal end of the shaft. The sealant may be stored within a reservoir of the applicator or pre-selected amounts of sealant can be individually loaded into the shaft.

In a specific embodiment, the sealant is heated by forcibly extruding it through a heated portion of the applicator shaft. As soon as the heated sealant reaches a certain viscosity, the melted, fluid sealant will readily flow through the shaft, where it is discharged from the distal end and applied to the wound. The melted sealant can be applied to the wound in continuous sheets, layers, films, strips, patches, etc. and will generally flow together to form a coalesced layer of molten sealant (glue) on the wound. A temperature sensor, such as a thermistor(s), may be disposed within the applicator shaft for controlling and monitoring the temperature of the sealant. The applicator may also include a mechanism for preventing discharge of the sealant until it reaches a suitable temperature.

One of the advantages of the present invention is that the sealant is provided with sufficient thermal energy (i.e., temperature and heat capacity) to denature surface proteins on the tissue without affecting more than several cell layers deep. In this manner, the damage to surrounding tissue will be clinically acceptable and the sealant will suitably bond with the tissue at the target site to seal the wound and approximate the tissue.

In an exemplary embodiment, the elongate shaft of the applicator is configured for introduction through a percutaneous penetration in the patient. In this manner, the methods and devices of the present invention can be used to enhance sealing of wounds within body cavities, such as punctures or incisions in muscle tissue or the serosal tissue surrounding body organs. Since energy is not directly applied to the tissue, the methods and devices of the present invention are particularly useful for closing wounds in the

pneumoreductions, etc.), in the gastrointestinal tract, (gastrectomies, intestinal/colon resection), in the liver, stomach, esophagus, uterus, ovaries, and in the spleen. In addition, the methods and devices may be used for closing suture holes in vessels, anastomosing two vessels together, bonding a skin graft to muscle tissue or tendons, reconstructing the fallopian tubes or other endoscopic or open surgical procedures. The present invention provides both secure mechanical closure of the wound and prevention or inhibition of fluid leakage, including both air leakage and liquid fluid leakage, such as blood and other bodily fluids. In addition, the sealant may provide a mechanical barrier between two tissue layers acting to prevent formation of adhesions between organs.

The present invention particularly relies on heating a sealant to a temperature sufficient to change its physical characteristics, thereby allowing the sealant to flow and to bond with the tissue. The heated, fluid sealant is applied to the region on the outer tissue surface surrounding the wound, where it flows over the inner wound surfaces and cools and sets to form suitable bonds with the tissue.

The sealant may be any natural, modified natural, or synthetic substance which has the ability to be heated into a non-solid state upon the application of energy from a suitable energy source, applied over the wound region and fused to the underlying tissue surrounding the closed. Thus, the sealant will be able to create and/or maintain a continuous film over (and sometimes penetrating into) the wound region to act both to mechanically enhance the wound closure and/or seal any perforations which may be present in the region. Such sealants should also be biocompatible (e.g., should be relatively non-toxic with low antigenicity and limited inflammatory activity) and usually (but not necessarily) will be bioabsorbable over time (e.g., being partially or completely resorbed into the underlying tissue over a period from, for example, 1 day to 90 days). Suitable synthetic materials include organic polymers which contain or have been modified to contain side groups which will bond (covalently or

visualization of the material during use and/or permit materials having different characteristics to be distinguished from each other. Other substances suitable for use as a component in the sealant include glycosaminoglycans, such as hyaluronic acid, dermatan sulfate, chondroitin sulfate, and heparin. Use of the glycosaminoglycans is desirable since such materials, which are anti-thrombotics, can reduce adhesion to adjacent tissues and organs. Other substances and additives may be included with the sealant for other purposes, as generally described in copending Application Serial No. 08/303,336, filed on September 9, 1994, the full disclosure of which has previously been incorporated herein by reference.

The method of the present invention will utilize energy of a type and in an amount sufficient to heat the sealant to a suitable temperature for bonding with the tissue. Suitable energy sources include electrical energy, particularly RF energy sources, microwave energy, heat energy, laser energy, ultrasonic energy, and the like. Energy from the energy source will typically be applied to the sealant before it is applied to the wound. The sealant will typically be exposed to the energy for a total time from about 1/10 of a second to 5 minutes, usually from 10 seconds to 3 minutes, for material having a volume from 1 cm^3 to 5 cm^3 for endoscopic procedures and 100 to 200 cm^3 for open procedures. The precise timing will depend on the composition of sealant and the temperature to which the sealant will be heated, as discussed below.

The sealant is heated to a temperature sufficient to melt the sealant and is then applied to the wound in a dispersible form, preferably a liquid. The temperature at which the sealant will melt depends on the type of sealant used and the composition of the overall formulation. The preferred formulation comprises collagen at 30 to 65 parts (w/w) and polyethyleneglycol (PEG) at 8 to 20 parts (w/w) with water making up the remaining component for a total of 100 parts. With this formulation, the collagen is typically

The liquid strips will flow together to form a coalesced layer of molten glue over substantially the entire open area of the wound.

When the liquid sealant is applied to the wound, it will preferably form both mechanical and chemical bonds with the tissue. Applicants believe that chemical bonds are formed by convalent bonding between the sealant and the underlying tissue proteins. Mechanical bonding occurs when the tissue elements are melted (i.e., proteins denatured) by heat transfer from the sealant. The molten tissue flows into holes and irregularities in the sealant and, when it cools and solidifies, it is trapped in these holes and irregularities so that the sealant and tissue are locked together. In addition, the melted sealant may flow into holes and crevices in the underlying tissue, which forms additional mechanical bonds when the sealant cools and solidifies.

Once the sealant has solidified, it will form a continuous sheet over the wound, thereby providing closure of the wound and inhibiting fluid leakage. For most of the materials described above, and in particular for the collagen and gelatin materials, the continuous sheet should have a thickness in the range from about 0.01 mm to 3.0 mm with a preferred thickness from 0.05 mm to 1.0 mm. Sealants having thicknesses generally greater than this range are less suitable since they display increasing stiffness.

Additional energy may be applied to the sealant after it has been introduced onto the wound to facilitate bonding the sealant to underlying tissue. Suitable energy sources include electrical energy, particularly RF energy sources, heat energy, laser energy, ultrasonic energy, and the like. Preferred are the use of RF energy sources, such as those available as electrosurgical power supplies from companies such as Valleylab, Boulder, Colorado, and Birtcher Medical Systems, Irvine, California, employing conventional RF-applying probes. Particularly preferred are modified radio frequency energy sources which provide for a dispersed or distributed current flow from a hand-held probe to the tissue.

Energy from the energy source will typically be

should have a length of 10-50 cm and preferably 35-45 cm for laparoscopic procedures and about 12-17 cm for open procedures. It should be noted that although shaft 2 is shown as having a circular cross-sectional shape in the drawings, shaft 22 could have a rectangular, oval, channel or other cross-sectional shape. In addition, shaft 22 may comprise a flexible tube with a rigid inner guide wire.

As shown in Fig. 2, applicator 10 includes a thermally and electrically insulating sheath 29 circumscribing shaft 22. Insulating sheath 29 preferably comprises a thermally dissipating material, such as ceramic or plastic. Shaft 22 has an axial passage 30 extending from distal end 24 to proximal end 26. Distal end 24 defines a frustoconical tip 28 having an opening 32 for discharging a sealant onto a wound or incision in the patient. Preferably, opening 32 has a circular or oval shape having a maximum radial dimension of about 1 to 4 mm. Shaft 22 may also include a variety of specialized tips for applying the sealant in different patterns on the wound, such as ribbons or circular caulk beads. In addition, shaft 22 may include a blade or other cutting means (not shown) on distal end 24 for cutting various amounts of sealant as it is discharged from shaft 18.

Proximal end 26 of shaft 22 is removably coupled to handle 20 so that shaft 22 can be removed from handle 20 for sterilization, disposal, etc. In addition, shaft 22 may be removed to load the sealant into a reservoir (not shown) within handle 20 or directly into the shaft, as discussed in more detail below. In the preferred embodiment, proximal end 26 has inner threads 34 that mate with threads 36 in handle 20. However, it will be readily recognized by those in the art that shaft may be removably coupled to handle in a variety of conventional manners, such as a ball detent mechanism or an annular rib around the outside of proximal end 26 for snapping shaft 22 into handle 20.

Shaft 22 comprises a heating element 40 for applying heat to the sealant before it is discharged through distal end 24. In the illustrative embodiment, the heating element comprises a distal portion of shaft 22, which is suitable

54 through shaft 22. It should be noted that a variety of conventional actuators can be utilized to propel the sealant through shaft 22, such as hand activated plungers, gas pressure, etc.

The method of the present invention will now be described in conjunction with Figs. 2 and 3A-3C. A solid sealant plug 54, preferably comprising a mixture of collagen, PEG and water as described above, is loaded into shaft 22 and proximal end 26 of shaft 22 is mounted to handle 20 of applicator 10, as shown in Fig. 2. Power supply 12 then provides a suitable current to the resistive heater within handle 20 and heating element 40 is heated to a suitable temperature for melting sealant plug 54. As shown in Fig. 3A, distal end 24 of shaft 22 is positioned adjacent a wound W in the patient. In an endoscopic procedure, shaft 22 will first be introduced through a percutaneous penetration in the patient, such as a cannula, and guided to the target site with visual assistance from an endoscope, usually a laparoscope, or other conventional viewing device.

Once distal end 24 of shaft 22 is suitably positioned adjacent the wound W, the surgeon will actuate trigger 56 and extrude sealant plug 54 through passage 30. In its solid state, plug 54 will frictionally engage the inner walls of passage 30, making it difficult to extrude the plug through shaft 22. As plug 54 passes through heating element 40, it will be melted, and the less viscous or fluid plug 54 will then be discharged through opening 32 onto the wound W. Thermistor(s) 44 monitors the temperature of fluid plug 54 and automatically prevents further discharge of the sealant if it becomes too hot. In addition, shaft 22 may include a stop mechanism for preventing the sealant from exiting tip 28 until it reaches a threshold temperature.

As shown in Fig. 3A, the sealant S is preferably applied generally parallel to the direction of the wound W. The wound is filled with the sealant, which begins to flow together to form a layer over the wound. The layer of glue will prevent fluid leakage through wound and it will begin to bond with the periphery tissue around wound W. As shown in

<u>WHAT IS CLAIMED IS</u>:

1. A method for applying a sealant material to a target site on tissue, said method comprising:

providing a reservoir of the sealant material;

heating the sealant material;

applying the heated sealant material to the target site; and

allowing the sealant material to cool and set at the target site.

2. The method of claim 1 wherein the sealant material is heated to a temperature sufficient to melt the sealant material.

3. The method of claim 1 wherein the sealant material is heated to a temperature sufficient to denature surface proteins on the tissue when the heated sealant is applied to the tissue.

4. The method of claim 1 wherein the sealant material is heated to a temperature sufficient to allow the sealant material to flow onto the wound.

5. The method of claim 1 wherein the sealant material is heated to a temperature greater than 60°C.

6. The method of claim 1 wherein the sealant material is heated to a temperature from 70°C to 110°C.

7. The method of claim 1 wherein the sealant material comprises at least one of a biologic polymer and a synthetic organic polymer.

8. The method of claim 7 wherein the sealant material is a biologic polymer comprising a protein selected from the group consisting of collagen, fibrin, fibrogen,

17. The method of claim 15 wherein the wound is a surgical incision or puncture.

18. The method of claim 15 wherein the wound is present in the serosal and underlying tissue of an internal body organ.

19. The method of claim 18 wherein the internal body organ is selected from the group consisting of small and large bowels, lungs, stomach, liver, esophagus, bladder, uterus, ovaries and spleen.

20. The method of claim 15 wherein the wound is present in muscle tissue.

21. The method of claim 1 wherein the heated sealant material is applied to at least one of the ends of first and second vessels, the method further comprising pressing the ends of the first vessel to the second vessel to bond the vessels to each other.

22. The method of claim 1 wherein the heated sealant material is applied to a hole in a vessel.

23. The method of claim 1 wherein the heated sealant material is applied between a skin graft and muscle tissue.

24. The method of claim 1 wherein the heated sealant material is applied onto a fallopian tube to recontruct said tube.

25. A method for closing a wound in tissue comprising:

housing a supply of sealant material within a reservoir of an applicator having a shaft with distal and proximal ends;

heating the sealant material;

32. The method of claim 25 wherein the discharging step includes extruding the melted sealant material onto the wound.

33. The method of claim 25 wherein the sealant material is heated to a temperature sufficient to denature surface proteins on the tissue when the sealant material is applied to the wound.

34. The method of claim 25 wherein the sealant material is heated to a temperature greater than 60°C.

35. The method of claim 25 wherein the sealant material is heated to a temperature from 70°C to 110°C.

36. The method of claim 25 wherein the sealant material comprises at least one of a biologic polymer and a synthetic organic polymer.

37. The method of claim 36 wherein the sealant material comprises a protein selected from the group consisting of collagen, fibrin, fibrogen, elastin, serum albumin, fibronectin, hemoglobin, ovalbumin and combinations thereof.

38. The method of claim 36 wherein the sealant material is a synthetic organic polymer selected from the group consisting of lactic acid, glycolic acid, hydroxybutyrate, phosphazine, polyester, polyethylene glycol, polyethylene oxide, polyacrylamide, polyhydroxyethylmethacrylate, poly-vinylpyrrolidon, poly-vinyl-alcohol, polyacrylic acid, polylactate, polycaprolactone, polypropylene, nylon and combinations thereof.

39. The method of claim 36 wherein the sealant material is present at from 25% to 75% by weight in a liquid carrier.

47. The apparatus of claim 45 wherein the applicator comprises a shaft which provides the sealant discharge lumen, the shaft having proximal and distal ends and a longitudinal axis therebetween, the distal end being configured for introduction through a percutaneous penetration in the patient.

48. The apparatus of claim 47 wherein the shaft has an outer diameter less than 12 mm and a length between 5 to 40 cm.

49. The apparatus of claim 47 wherein the heating element comprises a lumen disposed within the shaft near the distal end.

50. The apparatus of claim 45 wherein the applicator comprises a piston and means for actuating the piston to discharge sealant in the reservoir through the lumen.

51. The apparatus of claim 45 further comprising a temperature controller connected to receive a temperature signal from the temperature sensor and control power to the heating element, wherein the temperature controller has a set point selectable in at least the range from 70°C to 110°C.

52. An applicator for applying a sealant material to tissue comprising:

a reservoir for housing the sealing material;

a shaft for discharging the sealant material from the reservoir to the tissue, the shaft having proximal and distal ends and an inner lumen therebetween, the lumen being in fluid communication with the reservoir, the distal end of the shaft being configured for introduction through a percutaneous penetration in a patient; and

a heating element disposed within the lumen to heat the sealant material prior to discharge from the distal end of the shaft.

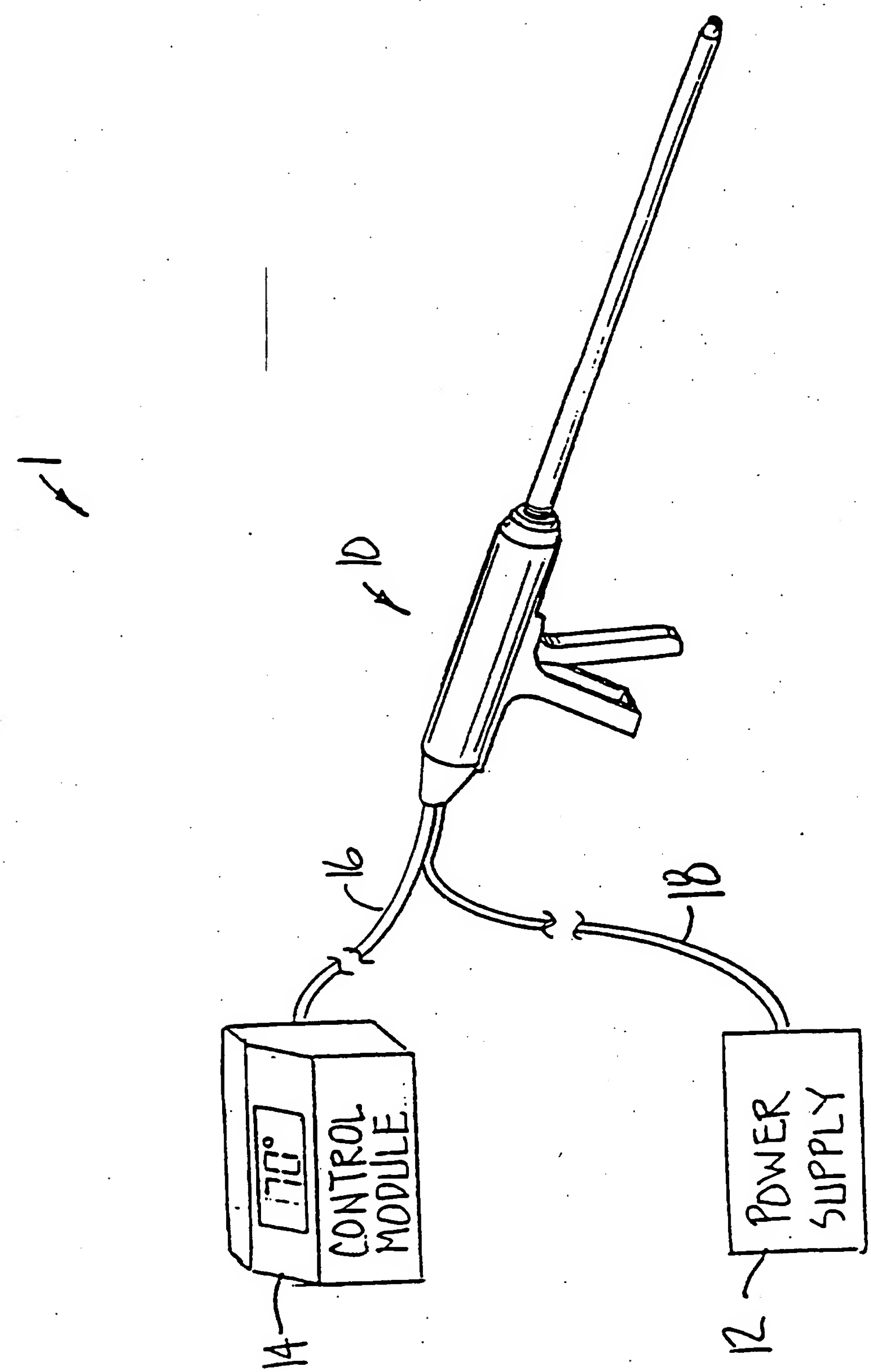


FIG. 1.

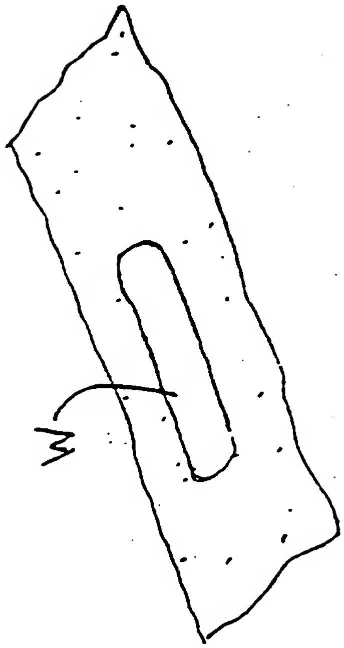


FIG. 3B.

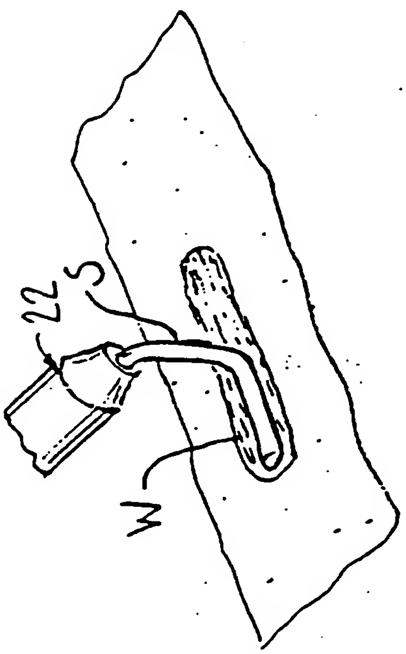


FIG. 3A.

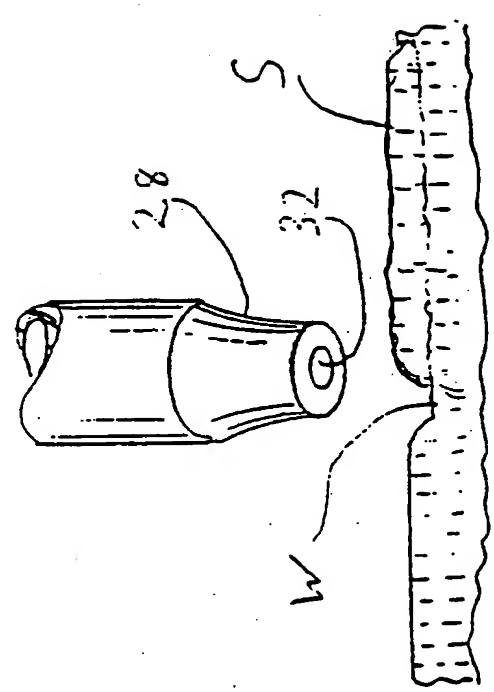


FIG. 3C.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/16185

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,324,305 A (KANNER) June 28, 1994, whole document.	1-4, 14, 15, 17, 26, 27, 29, 31, 32, 36, 42, 44 --- 5-13, 15-24, 30, 33-35, 37-41, 45-51, 58
Y	US 5,207,670 A (SINOFSKY) 04 May 1993, col. 2, lines 44-46.	8-13, 37-44, 58
Y	US 4,038,519 A (FOUCRAS) 26 July 1977, whole document.	14, 27, 30, 45-51, 53-58

CORRECTED VERSION*

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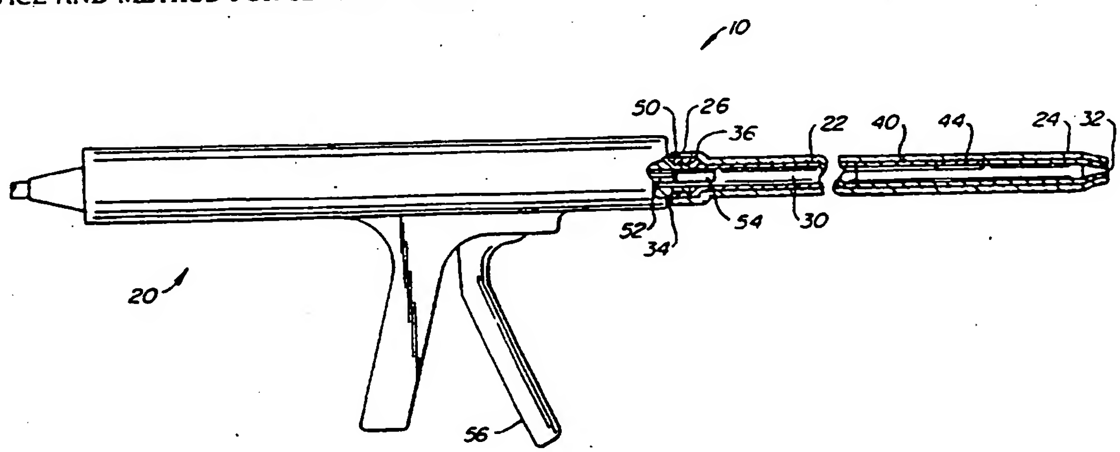

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DEVICE AND METHOD FOR SEALING TISSUE

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Most surgical disciplines are concerned with the repair of damaged tissues and vessels. Tissue damage can be the result of direct trauma to the body or as part of a surgical procedure in which there is a separation of normally continuous tissue such as blood vessels. Historically, suturing has been the accepted technique for rejoining severed tissues and closing wounds. To suture a wound, the surgeon manually stitches the surrounding tissue with a surgical needle and suturing thread, and more recently, with a variety of polymeric or metallic staples.

While suturing and stapling techniques are often successful, there are a number of limitations inherent in such mechanical approaches. The practice of suturing or stapling tissue together not only requires significant skill, but is a relatively slow process, particularly when extensive repair is required or when anastomosing tiny biological structures. Even when suturing is properly performed, however, this technique can be less than satisfactory because of the gaps which are left between the stitches and the possibility of progressive structural weakening over time. For example, the gaps leave the wound open to bacteria, producing a risk of infection. In addition, the suture needle or staples puncture the tissue, producing holes through which biological fluid may leak.

absorbed by the damaged tissue. The heat produced by absorption of the optical energy converts biological tissue into a denatured proteinaceous substance which forms a biological glue that closes the wound. Similar to cauterization techniques, however, the high intensity optical energy in this procedure creates a substantial risk of damaging neighboring tissues.

For these and other reasons, it would be desirable to provide procedures for effectively sealing damaged tissue structures, such as torn vessels or open wounds. These procedures should be capable of forming an immediate closure of the damaged tissue to prevent further blood leakage and creating a permanent seal around the wound, while minimizing damage or destruction of surrounding tissue.

2. Description of the Background Art

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In a specific embodiment, the sealant is heated by forcibly extruding it through a heated portion of the applicator shaft. As soon as the heated sealant reaches a certain viscosity, the melted, fluid sealant will readily flow through the shaft, where it is discharged from the distal end and applied to the wound. The melted sealant can be applied to the wound in continuous sheets, layers, films, strips, patches, etc. and will generally flow together to form a coalesced layer of molten sealant (glue) on the wound. A temperature sensor, such as a thermistor(s), may be disposed within the applicator shaft for controlling and monitoring the temperature of the sealant. The applicator may also include a mechanism for preventing discharge of the sealant until it reaches a suitable temperature.

One of the advantages of the present invention is that the sealant is provided with sufficient thermal energy (i.e., temperature and heat capacity) to denature surface proteins on the tissue without affecting more than several cell layers deep. In this manner, the damage to surrounding tissue will be clinically acceptable and the sealant will suitably bond with the tissue at the target site to seal the wound and approximate the tissue.

In an exemplary embodiment, the elongate shaft of the applicator is configured for introduction through a percutaneous penetration in the patient. In this manner, the methods and devices of the present invention can be used to enhance sealing of wounds within body cavities, such as punctures or incisions in muscle tissue or the serosal tissue surrounding body organs. Since energy is not directly applied to the tissue, the methods and devices of the present invention are particularly useful for closing wounds in the

pneumoreductions, etc.), in the gastrointestinal tract, (gastrectomies, intestinal/colon resection), in the liver, stomach, esophagus, uterus, ovaries, and in the spleen. In addition, the methods and devices may be used for closing suture holes in vessels, anastomosing two vessels together, bonding a skin graft to muscle tissue or tendons, reconstructing the fallopian tubes or other endoscopic or open surgical procedures. The present invention provides both secure mechanical closure of the wound and prevention or inhibition of fluid leakage, including both air leakage and liquid fluid leakage, such as blood and other bodily fluids. In addition, the sealant may provide a mechanical barrier between two tissue layers acting to prevent formation of adhesions between organs.

The present invention particularly relies on heating a sealant to a temperature sufficient to change its physical characteristics, thereby allowing the sealant to flow and to bond with the tissue. The heated, fluid sealant is applied to the region on the outer tissue surface surrounding the wound, where it flows over the inner wound surfaces and cools and sets to form suitable bonds with the tissue.

The sealant may be any natural, modified natural, or synthetic substance which has the ability to be heated into a non-solid state upon the application of energy from a suitable energy source, applied over the wound region and fused to the underlying tissue surrounding the closed. Thus, the sealant will be able to create and/or maintain a continuous film over (and sometimes penetrating into) the wound region to act both to mechanically enhance the wound closure and/or seal any perforations which may be present in the region. Such sealants should also be biocompatible (e.g., should be relatively non-toxic with low antigenicity and limited inflammatory activity) and usually (but not necessarily) will be bioabsorbable over time (e.g., being partially or completely resorbed into the underlying tissue over a period from, for example, 1 day to 90 days). Suitable synthetic materials include organic polymers which contain or have been modified to contain side groups which will bond (covalently or

visualization of the material during use and/or permit materials having different characteristics to be distinguished from each other. Other substances suitable for use as a component in the sealant include glycosaminoglycans, such as hyaluronic acid, dermatan sulfate, chondroitin sulfate, and heparin. Use of the glycosaminoglycans is desirable since such materials, which are anti-thrombotics, can reduce adhesion to adjacent tissues and organs. Other substances and additives may be included with the sealant for other purposes, as generally described in copending Application Serial No. 08/303,336, filed on September 9, 1994, the full disclosure of which has previously been incorporated herein by reference.

The method of the present invention will utilize energy of a type and in an amount sufficient to heat the sealant to a suitable temperature for bonding with the tissue. Suitable energy sources include electrical energy, particularly RF energy sources, microwave energy, heat energy, laser energy, ultrasonic energy, and the like. Energy from the energy source will typically be applied to the sealant before it is applied to the wound. The sealant will typically be exposed to the energy for a total time from about 1/10 of a second to 5 minutes, usually from 10 seconds to 3 minutes, for material having a volume from 1 cm^3 to 5 cm^3 for endoscopic procedures and 100 to 200 cm^3 for open procedures. The precise timing will depend on the composition of sealant and the temperature to which the sealant will be heated, as discussed below.

The sealant is heated to a temperature sufficient to melt the sealant and is then applied to the wound in a dispersible form, preferably a liquid. The temperature at which the sealant will melt depends on the type of sealant used and the composition of the overall formulation. The preferred formulation comprises collagen at 30 to 65 parts (w/w) and polyethyleneglycol (PEG) at 8 to 20 parts (w/w) with water making up the remaining component for a total of 100 parts. With this formulation, the collagen is typically

The liquid strips will flow together to form a coalesced layer of molten glue over substantially the entire open area of the wound.

When the liquid sealant is applied to the wound, it will preferably form both mechanical and chemical bonds with the tissue. Applicants believe that chemical bonds are formed by convalent bonding between the sealant and the underlying tissue proteins. Mechanical bonding occurs when the tissue elements are melted (i.e., proteins denatured) by heat transfer from the sealant. The molten tissue flows into holes and irregularities in the sealant and, when it cools and solidifies, it is trapped in these holes and irregularities so that the sealant and tissue are locked together. In addition, the melted sealant may flow into holes and crevices in the underlying tissue, which forms additional mechanical bonds when the sealant cools and solidifies.

Once the sealant has solidified, it will form a continuous sheet over the wound, thereby providing closure of the wound and inhibiting fluid leakage. For most of the materials described above, and in particular for the collagen and gelatin materials, the continuous sheet should have a thickness in the range from about 0.01 mm to 3.0 mm with a preferred thickness from 0.05 mm to 1.0 mm. Sealants having thicknesses generally greater than this range are less suitable since they display increasing stiffness.

Additional energy may be applied to the sealant after it has been introduced onto the wound to facilitate bonding the sealant to underlying tissue. Suitable energy sources include electrical energy, particularly RF energy sources, heat energy, laser energy, ultrasonic energy, and the like. Preferred are the use of RF energy sources, such as those available as electrosurgical power supplies from companies such as Valleylab, Boulder, Colorado, and Birtcher Medical Systems, Irvine, California, employing conventional RF-applying probes. Particularly preferred are modified radio frequency energy sources which provide for a dispersed or distributed current flow from a hand-held probe to the tissue.

Energy from the energy source will typically be

should have a length of 10-50 cm and preferably 35-45 cm for laparoscopic procedures and about 12-17 cm for open procedures. It should be noted that although shaft 2 is shown as having a circular cross-sectional shape in the drawings, shaft 22 could have a rectangular, oval, channel or other cross-sectional shape. In addition, shaft 22 may comprise a flexible tube with a rigid inner guide wire.

As shown in Fig. 2, applicator 10 includes a thermally and electrically insulating sheath 29 circumscribing shaft 22. Insulating sheath 29 preferably comprises a thermally dissipating material, such as ceramic or plastic. Shaft 22 has an axial passage 30 extending from distal end 24 to proximal end 26. Distal end 24 defines a frustoconical tip 28 having an opening 32 for discharging a sealant onto a wound or incision in the patient. Preferably, opening 32 has a circular or oval shape having a maximum radial dimension of about 1 to 4 mm. Shaft 22 may also include a variety of specialized tips for applying the sealant in different patterns on the wound, such as ribbons or circular caulk beads. In addition, shaft 22 may include a blade or other cutting means (not shown) on distal end 24 for cutting various amounts of sealant as it is discharged from shaft 18.

Proximal end 26 of shaft 22 is removably coupled to handle 20 so that shaft 22 can be removed from handle 20 for sterilization, disposal, etc. In addition, shaft 22 may be removed to load the sealant into a reservoir (not shown) within handle 20 or directly into the shaft, as discussed in more detail below. In the preferred embodiment, proximal end 26 has inner threads 34 that mate with threads 36 in handle 20. However, it will be readily recognized by those in the art that shaft may be removably coupled to handle in a variety of conventional manners, such as a ball detent mechanism or an annular rib around the outside of proximal end 26 for snapping shaft 22 into handle 20.

Shaft 22 comprises a heating element 40 for applying heat to the sealant before it is discharged through distal end 24. In the illustrative embodiment, the heating element comprises a distal portion of shaft 22, which is suitable

54 through shaft 22. It should be noted that a variety of conventional actuators can be utilized to propel the sealant through shaft 22, such as hand activated plungers, gas pressure, etc.

The method of the present invention will now be described in conjunction with Figs. 2 and 3A-3C. A solid sealant plug 54, preferably comprising a mixture of collagen, PEG and water as described above, is loaded into shaft 22 and proximal end 26 of shaft 22 is mounted to handle 20 of applicator 10, as shown in Fig. 2. Power supply 12 then provides a suitable current to the resistive heater within handle 20 and heating element 40 is heated to a suitable temperature for melting sealant plug 54. As shown in Fig. 3A, distal end 24 of shaft 22 is positioned adjacent a wound W in the patient. In an endoscopic procedure, shaft 22 will first be introduced through a percutaneous penetration in the patient, such as a cannula, and guided to the target site with visual assistance from an endoscope, usually a laparoscope, or other conventional viewing device.

Once distal end 24 of shaft 22 is suitably positioned adjacent the wound W, the surgeon will actuate trigger 56 and extrude sealant plug 54 through passage 30. In its solid state, plug 54 will frictionally engage the inner walls of passage 30, making it difficult to extrude the plug through shaft 22. As plug 54 passes through heating element 40, it will be melted, and the less viscous or fluid plug 54 will then be discharged through opening 32 onto the wound W. Thermistor(s) 44 monitors the temperature of fluid plug 54 and automatically prevents further discharge of the sealant if it becomes too hot. In addition, shaft 22 may include a stop mechanism for preventing the sealant from exiting tip 28 until it reaches a threshold temperature.

As shown in Fig. 3A, the sealant S is preferably applied generally parallel to the direction of the wound W. The wound is filled with the sealant, which begins to flow together to form a layer over the wound. The layer of glue will prevent fluid leakage through wound and it will begin to bond with the periphery tissue around wound W. As shown in

WHAT IS CLAIMED IS:

1. A method for applying a sealant material to a target site on tissue, said method comprising:

providing a reservoir of the sealant material;

heating the sealant material;

applying the heated sealant material to the target site; and

allowing the sealant material to cool and set at the target site.

2. The method of claim 1 wherein the sealant material is heated to a temperature sufficient to melt the sealant material.

3. The method of claim 1 wherein the sealant material is heated to a temperature sufficient to denature surface proteins on the tissue when the heated sealant is applied to the tissue.

4. The method of claim 1 wherein the sealant material is heated to a temperature sufficient to allow the sealant material to flow onto the wound.

5. The method of claim 1 wherein the sealant material is heated to a temperature greater than 60°C.

6. The method of claim 1 wherein the sealant material is heated to a temperature from 70°C to 110°C.

7. The method of claim 1 wherein the sealant material comprises at least one of a biologic polymer and a synthetic organic polymer.

8. The method of claim 7 wherein the sealant material is a biologic polymer comprising a protein selected from the group consisting of collagen, fibrin, fibrogen,

17. The method of claim 15 wherein the wound is a surgical incision or puncture.

18. The method of claim 15 wherein the wound is present in the serosal and underlying tissue of an internal body organ.

19. The method of claim 18 wherein the internal body organ is selected from the group consisting of small and large bowels, lungs, stomach, liver, esophagus, bladder, uterus, ovaries and spleen.

20. The method of claim 15 wherein the wound is present in muscle tissue.

21. The method of claim 1 wherein the heated sealant material is applied to at least one of the ends of first and second vessels, the method further comprising pressing the ends of the first vessel to the second vessel to bond the vessels to each other.

22. The method of claim 1 wherein the heated sealant material is applied to a hole in a vessel.

23. The method of claim 1 wherein the heated sealant material is applied between a skin graft and muscle tissue.

24. The method of claim 1 wherein the heated sealant material is applied onto a fallopian tube to recontruct said tube.

25. A method for closing a wound in tissue comprising:

housing a supply of sealant material within a reservoir of an applicator having a shaft with distal and proximal ends;

heating the sealant material;

32. The method of claim 25 wherein the discharging step includes extruding the melted sealant material onto the wound.

33. The method of claim 25 wherein the sealant material is heated to a temperature sufficient to denature surface proteins on the tissue when the sealant material is applied to the wound.

34. The method of claim 25 wherein the sealant material is heated to a temperature greater than 60°C.

35. The method of claim 25 wherein the sealant material is heated to a temperature from 70°C to 110°C.

36. The method of claim 25 wherein the sealant material comprises at least one of a biologic polymer and a synthetic organic polymer.

37. The method of claim 36 wherein the sealant material comprises a protein selected from the group consisting of collagen, fibrin, fibrogen, elastin, serum albumin, fibronectin, hemoglobin, ovalbumin and combinations thereof.

38. The method of claim 36 wherein the sealant material is a synthetic organic polymer selected from the group consisting of lactic acid, glycolic acid, hydroxybutyrate, phosphazine, polyester, polyethylene glycol, polyethylene oxide, polyacrylamide, polyhydroxyethylmethacrylate, poly-vinylpyrrolidon, poly-vinyl-alcohol, polyacrylic acid, polylactate, polycaprolactone, polypropylene, nylon and combinations thereof.

39. The method of claim 36 wherein the sealant material is present at from 25% to 75% by weight in a liquid carrier.

47. The apparatus of claim 45 wherein the applicator comprises a shaft which provides the sealant discharge lumen, the shaft having proximal and distal ends and a longitudinal axis therebetween, the distal end being configured for introduction through a percutaneous penetration in the patient.

48. The apparatus of claim 47 wherein the shaft has an outer diameter less than 12 mm and a length between 5 to 40 cm.

49. The apparatus of claim 47 wherein the heating element comprises a lumen disposed within the shaft near the distal end.

50. The apparatus of claim 45 wherein the applicator comprises a piston and means for actuating the piston to discharge sealant in the reservoir through the lumen.

51. The apparatus of claim 45 further comprising a temperature controller connected to receive a temperature signal from the temperature sensor and control power to the heating element, wherein the temperature controller has a set point selectable in at least the range from 70°C to 110°C.

52. An applicator for applying a sealant material to tissue comprising:

a reservoir for housing the sealing material;

a shaft for discharging the sealant material from the reservoir to the tissue, the shaft having proximal and distal ends and an inner lumen therebetween, the lumen being in fluid communication with the reservoir, the distal end of the shaft being configured for introduction through a percutaneous penetration in a patient; and

a heating element disposed within the lumen to heat the sealant material prior to discharge from the distal end of the shaft.

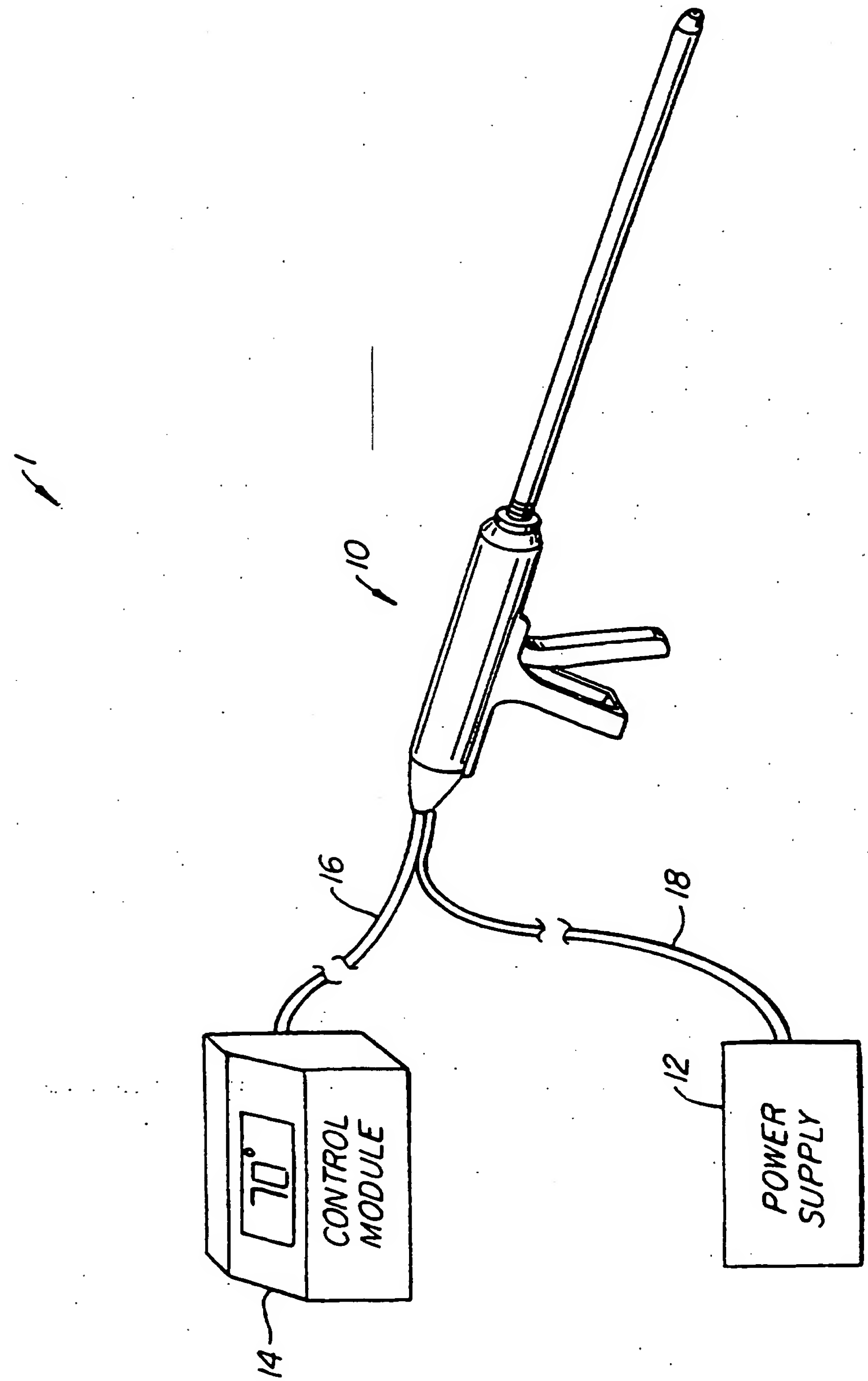

FIG. 1.

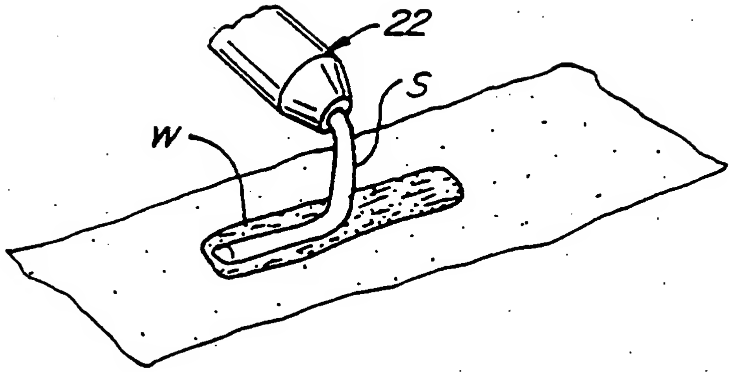

FIG. 3A.

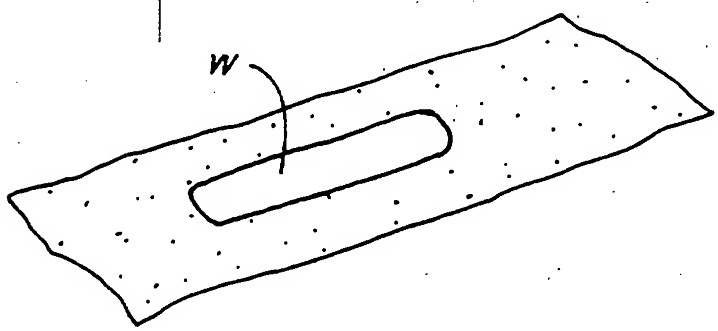

FIG. 3B.

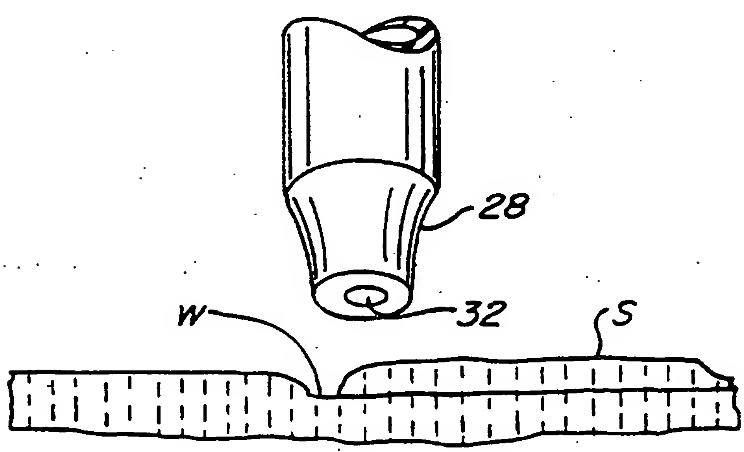

FIG. 3C.

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,324,305 A (KANNER) June 28, 1994, whole document.	1-4, 14, 15, 17, 26, 27, 29, 31, 32, 36, 42, 44 --- 5-13, 15-24, 30, 33-35, 37-41, 45-51, 58
Y	US 5,207,670 A (SINOFSKY) 04 May 1993, col. 2, lines 44-46.	8-13, 37-44, 58
Y	US 4,038,519 A (FOUCRAS) 26 July 1977, whole document.	14, 27, 30, 45-51, 53-58